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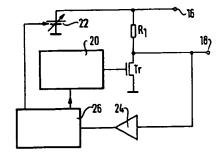
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Applicant: Slemens Elema AB Röntgenvägen 2 S-171 95 Solna 1 (SE)

Inventor: Strandberg, Hans Landsvägen 51 S-172 36 Sundbyberg (SE)

- (S) Method and device for measuring the flow of an electrolytic fluid.
- (3) In a method for measuring the flow of an electrolytic fluid, the voltage or current is measured between two stationary electrodes immersed in the electrolyte. A device for measuring the flow comprises at least two electrodes (16, 18) intended for immersion in the electrolyte. The electrodes are stationary, and a measurement unit (26) is arranged to measure the voltage or current between the electrodes.

FIG 3



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This invention relates to a method and a device for measuring the flow of an electrolytic fluid, at least two electrodes then being immersed in the electrolyte.

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This type of flow measurement has a number of industrial and medical applications, such as the measurement of blood flow for rate-responsive control of a pacemaker and in conjunction with the detection of tachycardia. Blood flow is reduced in tachycardia.

This type of flow measurement has previously been performed by e.g. thermodilution, the cooling of a heated electrode by fluid flowing around it then being studied. The electrode can be heated and the temperature in the medium can be e.g. alternately sensed. Performing such flow measurements with the aid of Doppler sound measurement is also previously known. Both these prior art methods require relatively complex equipment.

The object of the present invention is to achieve a new method and a new device for measuring the flow of an electrolytic fluid which are considerably simpler and require simpler and, thus, cheaper measurement equipment.

This object is achieved with a method and a device of the kind described in the introduction with the characterizing features set forth in claims 1 and 6 respectively.

The method and device according to the invention are based on the circumstance that an EMF develops between electrodes when electrodes made of a suitable material are immersed in an electrolyte, such as a saline solution. This EMF, or more accurately, the terminal voltages arising between the respective electrode and the electrolyte and giving rise to the resulting EMF, depends on the flow of fluid around the electrode.

The advantages of the invention lies in its simplicity. The measurement equipment required is simple, and an existing pacemaker electrode, if of the right type, can be employed when the invention is used for measurement of blood flow for pacemakers. Thus, a bipolar electrode with e.g. a carbon tip and platinum ring, has been found to function very well for such measurement of blood flow according to the invention.

According to an advantageous refinement of the method according to the invention, a continuous or recurrent pulsed current, providing a net direct correct, is applied to the electrodes, and the resulting voltage between the electrodes, which depends on the flow of fluid, is measured. In this manner, the electrode system is "charged" with an EMF.

After a long period of time, the unloaded EMF amounts to about 40-50 mV. If, in the measurement procedure, the system is pulsed with a few volts whose pulse duration lasts a fraction of 1 ms, an

EMF of less than 1 mV arises with a recharge constant of the order of minutes.

According to another advantageous embodiment of the method according to the invention, the pulse duration is regulated so the measured voltage becomes appropriate to the application in question.

However, stimulation till a stable, elevated EMF is achieved provides a very good possibility for detecting flow. The flow-dependent variation in EMF amounts to about 50 mV.

Measurement of flow can also be performed by compensatorily adjustment of the pulse amplitude to keep the EMF voltage stable. Experiments have been made at a 0.5 V EMF and a 1 V EMF level. Changes in pulse voltage of 1 - 2 V were then required between a fast fluid flow and a stagnant fluid flow.

According to another advantageous embodiment of the method according to the invention, voltage between the electrodes is kept constant, and the current between the electrodes is measured. Since the charge transferred is a measure of the fluid flow, an increased flow results in an increase in current.

No saturation has been observed. Both a zero flow current and sensitivity, i.e. current/flow rate, depend on the fluid and the electrodes used and the voltage applied. The measurement current is of the order of 50 -500 nA.

When the invention is applied to a pacemaker, it must be kept in mind that the EMF, or terminal voltages, is greatly dependent on the stimulation pulses emitted. However, compensating for this is not very difficult, since the stimulation rate is deterministic and measurable, and measurement of current or voltage is performed immediately prior to the emission of a stimulation pulse according to an advantageous example of the method according to the invention. Studies have shown that the post-polarization course is not dependent on the fluid flow.

The voltage, which can be characterized as electrode EMF, is material-dependent. A reduction, harmless to the electrode material, occurs at the negative electrode. However, an oxidation occurring at the positive electrode can cause dissolution of the material, i.e. the electrode can be eaten away. So the positive electrode must be made of a non-reactive material. Therefore, the choice of electrode material must be made with care, as well as the choice of current direction, for the flow measurement.

According to an advantageous embodiment of the device according to the invention when used with pacemakers, the electrodes consist of a bipolar pacemaker electrode with a carbon tip and a platinum ring. Practical tests with this electrode 10

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configuration have yielded excellent flow measurement results.

The invention will now be explained in greater detail, with reference to the attached drawings illustrating embodiments. Thus,

FIG. 1 shows a pair of electrodes in an electrolyte to illustrate the invention's basic principle; FIG. 2 shows an example of a circuit for performing the voltage measurement required for determining the flow;

FIGS. 3 and 4 show examples of measurement circuits in the device according to the invention;

FIG. 5 schematically depicts a pacemaker or defibrillator with the device according to the invention;

FIG. 6 is a block diagram of a pacemaker or defibrillator with the device according to the invention; and

FIG. 7 is a block diagram of an example of the flow measurement device according to the invention in the version shown in FIG. 6.

In FIG. 1 is shown two electrodes 2, 4 immersed in an electrolyte 6, e.g. a 0.5% saline solution.

When suitable electrodes are chosen, an EMF, which depends on the flow of electrolyte 6, develops between the electrodes 2, 4. More precisely flow-dependent terminal voltages develop between the electrode 2, 4 and the electrolyte, resulting in the EMF.

In FIG. 1, a voltage U is applied across the electrodes 2, 4, and the current I is intended to be measured and its magnitude constitutes a measure of the flow of the electrolyte.

The principle of the invention can be illustrated with the device shown in FIG. 1 by stirring the electrolyte 6 with e.g. a magnetic stirrer in order to provide a flow in the electrolyte 6 container.

The current I through the pair of electrodes (regarded as corresponding voltage) can be measured with the circuit shown in FIG. 2, a suitable recording instrument being connected to DVM. A reference image memory oscilloscope, i.e. an oscilloscope supplied with a normal pulse to which measured pulses can be compared to make deviations readily discernible to the eye, can be used as such a recording instrument.

When the circuit in FIG. 2 is used in a pace-maker with a bipolar electrode, the output terminal 8 is connected to the tip of the stimulating electrode, appropriately a carbon tip, and the output terminal 10 is connected to the sensing electrode, appropriately a platinum ring. The control voltage is supplied by the voltage source 12, and the voltage between output terminals 8 and 10 is measured with the feedback amplifier 14.

A lack of dissolved oxygen in the electrolyte has been found to produce unstable, non-reproduc-

ible results. So oxygen must be present dissolved in the electrolyte if flow measurement according to the invention shall operate reliably. Moreover, the pH value of the electrolyte has been found to affect the sensitivity of flow measurement. The limit value for reliable measurement with the method and device according to the invention is a pH of about 5, a more acidic solution impairing sensitivity. The processes at the two electrodes are:

$$2OH^- \rightarrow H_2O + \frac{1}{2}O_2 + 2e^-$$
 oxidation

$$H_2O + \frac{1}{2}O_2 + 2e^- \rightarrow 2OH^-$$
 reduction

With a constant voltage between the two electrodes, any change in the normal potential of an electrode will also cause a change in the normal potential of the other electrode. The sensitivity to voltage changes of the oxidation process above increases as the solution becomes more acidic due to the lower concentration of hydroxide ions.

Experiments have also shown that the flow sensing primarily occurs at the positive electrode, whereas the negative electrode controls the current.

In FIG. 3 is shown a version of the device according to the invention, intended for use in a pacemaker, for the measurement of blood flow. This embodiment is intended for pulsed or sampled flow measurement.

In the circuit according to FIG. 3, the output terminal 16 is connected to the indifferent electrode, suitably a platinum ring, and the output terminal 18 to the stimulation electrode, suitably a carbon tip, cf. the description of FIG. 2.

A high-resistance resistor R₁ is connected between the output terminals 16, 18, and the electrode connected to the output terminal 18 is charged with charging pulses by the switching transistor Tr. Thus, these pulses are emitted by the same electrode as the pacemaker's stimulation pulses but at different times.

The switching transistor Tr is controlled by the control electronics 20.

An FET amplifier 24 and the following measurement and control electronics 26 are connected to the output terminal 18 to control the voltage source 22 and for the measurement. The measurement and control electronics 26 are further connected to the transistor's Tr control electronics 20. In this way control of both the transistor Tr and the voltage source 22 is possible depending on the voltage measured.

In FIG. 4 is shown an embodiment intended for continuous supply of current to the electrodes. Here, the indifferent electrode is connected to the output terminal 28 and the stimulation electrode to the output terminal 30.

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The source of voltage 32, connected in series with a high-resistance resistor R_2 , is connected between the output terminals 28, 30.

In the corresponding manner as in the version in FIG. 3, an FET amplifier 34 and following measurement and control electronics 36 are connected to the output terminal 30 for measurement and control purposes. Also in this instance, the source of voltage 32 is controllable, depending on the voltage measured between the electrodes.

In FIG. 5 is shown a pacemaker or defibrillator 38 with a conventional bipolar electrode with an indifferent ring 40 and a stimulation pole 42. The pacemaker or defibrillator 38 is equipped with a device according to the invention, and the ring 40 for this purpose is appropriately made of platinum and the pole 42 of carbon.

Practical tests have been made with a platinum ring with a contact area of about $32~\text{mm}^2$ and a carbon tip with a $6~\text{mm}^2$ contact area .

In FIG. 6 is shown a block diagram of the pacemaker or defibrillator 38 of FIG. 5.

The pacemaker section 44 is connected with its stimulation output terminal 46, via an output capacitor C_0 , to the output terminal 48 for the stimulation electrode. Heart signals are received at the same output terminal 48 and supplied via a filter 50 with a capacitor C_1 to the pacemaker section 44 via its input 52 for heart signal detection

The pacemaker or defibrillator 38 further contains a flow measurement unit 54 with an output 56 connected to the output 48 in order to supply the stimulation electrode with a bias signal in conjunction with the flow measurement. The voltage measurement signal required for measurement of the flow is received by the flow measurement unit via the input terminal 58.

Special control electronics 60 are provided to control the pacemaker section 44, in response to the flow measurement unit 54.

Both the pacemaker section 44 and the flow measurement unit 54 are further connected, via outputs 62, 64, to the output 66, intended to be connected to the indifferent electrode 40 in FIG. 5.

In FIG. 7 is shown the flow measurement unit 54 in greater detail. Thus, the flow measurement unit 54 contains signal-generating electronics 68 for supplying, via the output 56 and the output 48, the electrode with currents or voltages required for measurement of the flow, as discussed above. The measurement signal for the flow measurement is received via the output 48 and the input 58 and sent via a buffer amplifier 70 to the measurement and control electronics 72 which treat and analyze the measurement signal in an appropriate manner and deliver an output signal on the output 74 representing the measured flow value. The mea-

surement and control electronics 72 are also connected to the signal-generating electronics 68 to control their function, in response to the measurement signals received.

Claims

- A method for measuring the flow of an electrolytic fluid (6), characterized in that the voltage or the current is measured between two stationary electrodes (2, 4; 40, 42) immersed in the electrolyte.
- A method of claim 1, characterized in that a continuous or pulsed current is supplied to the electrodes (2, 4; 40, 42), and the resulting voltage between the electrodes is measured.
- 3. A method of claim 2, in which polarized pulses are delivered to the electrodes (24; 40, 42), characterized in that the pulse duration is adjusted in such a way that the measured voltage is of appropriate magnitude for the application in question.
- 4. A method of claim 1, characterized in that the voltage between the electrodes (2, 4; 40, 42) is kept constant, and the current between the electrodes is measured.
- 5. A method of claim 1, applied to a pacemaker (38), for measurement of blood flow, characterized in that the measurement of current or voltage intented for determination of the flow is performed immediately prior to delivery of a stimulation pulse.
- 6. A device for measuring the flow of an electro-lytic fluid (6), containing at least two electrodes (2, 4; 40, 42) intended for immersion in the electrolyte, characterized in that the electrodes (2, 4; 40, 42) are stationary, and in that a measurement unit (14; 24, 26; 34, 36; 54) is devised to measure the voltage or current between the electrodes.
- A device of claim 6, characterized in that means (68) are devised to deliver pulses to one (42) of the electrodes, the pulse duration being such that a certain constant level of voltage is measured between the electrodes (40, 42).
- 8. A device of claim 6 or 7, arranged in a pace-maker (38), for measuring the blood flow, the electrodes (40, 42) being formed of the poles of a pacemaker electrode, characterized in that the poles (40, 42) are made of carbon and

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platinum.

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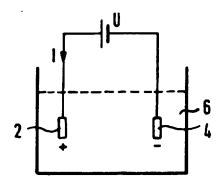


FIG 2

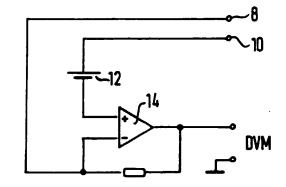
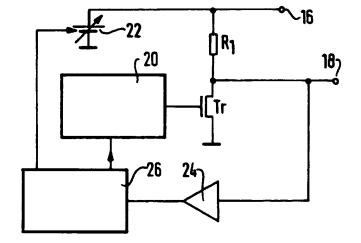
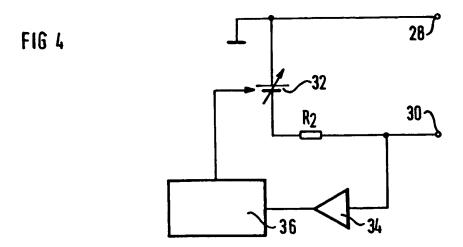
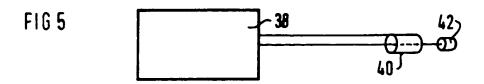
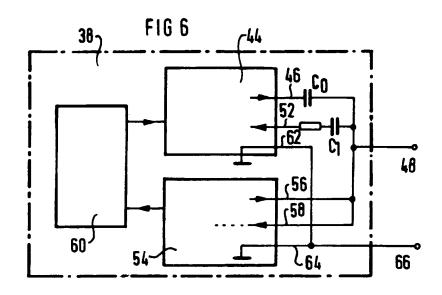


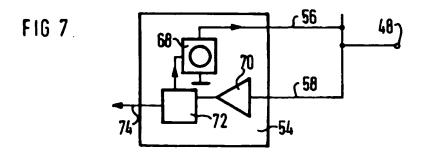
FIG 3













EUROPEAN SEARCH REPORT

Application Number EP 94 10 0130

ategory	Citation of document with indic	ation, where appropriate,	Relevant to claim	CLASSIFICATION OF THE APPLICATION (InlCL5)	
(EP-A-O 077 413 (MEMOT CANCER AND ALLIED DIS * page 6, line 19 - p	IAL HOSPITAL FOR EASES)	1-4,6,7	G01F1/56 G01P5/08 A61B5/026	
1	page o, Time 15 p		5,8	A61N1/36	
ſ	EP-A-0 310 026 (A. EC * column 9, line 44 - 20,28,29 *	KHARD) line 52; claims	5,8		
(US-A-3 450 984 (J.F. * claim 1 *	HOLMES)	1-4,6,7		
4	US-A-5 174 299 (J.P. * column 6, line 26 -	NELSON) line 38 *	1-8		
A	EP-A-0 049 027 (E.M. * abstract *	REIMER)	1-4,6,7		
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				TECHNICAL FIELDS SEARCHED (Int.Cl.5)	
				G01F	
				GO1P	
				A61B A61N	
	The present search report has been	drawn up for all claims			
Place of search Date of com		Date of completion of the search		Executary	
STOCKHOLM 4 M		4 May 1994		EKDAHL HARRIET	
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